REMARKS

Claims 1, 3, 4, and 6 have been amended to obviate the drawing objection and to more clearly distinguish over the cited references. No claim has been added or deleted. Support for the claim amendments may be found throughout the specification and particularly in paragraph [0024]. No new matter has been added. Upon entry of the above amendments, claims 1-7 will remain in the application.

Drawing Objection

The drawings stand objected to under 37 CFR 1.83(a) as allegedly not showing the claimed "first and second lumens." The claims have been amended to obviate the objection.

Applicant notes that Figures 3 and 4 clearly show at least one lumen for accepting the foldable membrane and for cardioplegia delivery. Paragraph [0024] of the specification, on the other hand, recites that the cardioplegia cannula includes a "coaxial needle" suggesting coaxial lumens as well as "an additional lumen containing a nitinol wire" that is in addition to the central lumen of the catheter 32 whereby the "nitinol umbrella 36 (in folded position) is advanced through the second lumen into the aorta just above the aortic valve" (lines 4-10). In view of this disclosure, claims 1, 3, 4, and 6 have been amended to recite "at least one lumen" for cardioplegia delivery and for advancing the folded membrane through the catheter. Those skilled in the art would readily appreciate that a catheter with one or more lumens (coaxial, double D, or of other known shapes) may be used for delivery of the cardioplegia solution, coaxial needle, and folded membrane to the aortic root based on such teachings. The figures have accordingly not been amended. No new matter has been added by these claim amendments.

In view of the amendments to claims 1, 3, 4, and 6, all of the claim features are believed to be clearly shown in the figures as described in the specification. Withdrawal of the objection to the drawings is solicited.

Claim Rejections – 35 USC § 103(a)

Claims 1-3 and 7 stand rejected under 35 USC § 103(a) as allegedly being unpatentable as obvious over US 5,013,296 ("Buckberg") in view of US 6,267,747 ("Samson"). These rejections are traversed.

Independent claims 1 and 3 have been amended to clarify that the inserted membrane "prevents the cardioplegia solution from entering the left ventricle through the aortic valve

and the membrane traps the cardioplegia solution above the membrane and below the cross-clamp so as to force the cardioplegia solution down the coronary arteries." In other words, the membrane is located downstream from the cardioplegia delivery position so as to prevent the cardioplegia solution from passing through an incompetent aortic valve into the left ventricle while simultaneously forcing the cardioplegia solution down the coronary arteries as desired. Such features are not shown or suggested by the cited references.

Buckberg discloses a conventional cardioplegia cannula that is inserted into the aortic root beneath a clamp for administration of cardioplegia solution. Such a device is quite similar to that illustrated in prior art Figure 2 of the present application. As acknowledged by the examiner at page 3 of the Official Action, Buckberg does not disclose a lumen "adapted to accept a folded non-porous membrane to cover the aortic valve nor the use of such a membrane." Applicant further notes that Buckberg does not recognize or address the problem of leakage of cardioplegia solution into the left ventricle through the aortic valve during administration of the cardioplegia solution.

To address such shortcomings in the teachings of Buckberg, the examiner cites Samson's teachings of an aortic catheter that uses a balloon to occlude blood flow in the aortic root and concludes that one skilled in the art would have modified the cannula of Buckberg to deliver a balloon as taught by Samson to block the aortic root and aortic valve to prevent the aortic root from experiencing significant retrograde fluid pressure. Applicant respectfully disagrees with the examiner's conclusions from the teachings of Buckberg and Samson. In any case, the amendments to the claims are believed to clearly different the claimed method and cardioplegia cannula from the teachings of Buckberg and Samson.

In particular, as is clear from Figure 5 of the present application and the related discussion in paragraph [0024] of the specification, the claimed methods and cannula address the problem of leakage through the aortic valve during cardioplegia delivery. Neither Buckberg nor Samson addresses this issue. As noted by the examiner, Samson teaches that by delivering cardioplegia solution directly to the coronary arteries that Samson's aortic root balloon perfusion catheter purportedly does not cause significant retrograde fluid pressure that would cause cardioplegia solution to be forced through the aortic valve into the left ventricle. However, Applicant notes further that Samson does not account for an incompetent or open aortic valve that would leak even if "significant retrograde fluid

pressure" were not created. Samson thus does not address the problem addressed by the claimed method and cannula.

Moreover, the geometry of the cannula disclosed by Samson would preclude the possibility of inserting a membrane through Samson's or Buckberg's catheter that would trap the cardioplegia solution "above the membrane and below the cross-clamp so as to force the cardioplegia solution down the coronary arteries" as claimed. This is the case because, as acknowledged by the examiner, Samson uses a distal flow control member in the form of a porous aortic root member that is configured to deliver the cardioplegia solution to the coronary ostia while occluding the ascending aorta. When in place, the cannula of Samson occludes the ascending aorta with the expanded balloon of the aortic root balloon perfusion catheter but does not provide anything to occlude the leakage of cardioplegia fluid through the aortic valve into the left ventricle. Also, as noted at column 6, lines 41-55, the porous root balloon is mounted distally and delivers the cardioplegia solution through a porous material 126 of the porous root balloon to provide a controlled volume of fluid that may perfuse the coronary arteries. Since Samson is concerned with controlling the flow of cardioplegia fluid to the aortic valve to avoid significant retrograde fluid pressure, it is clear that Samson did not teach or contemplate using a membrane or the inflated balloon to trap the cardioplegia solution above the membrane and below the cross-clamp so as to force the cardioplegia solution down the coronary arteries as claimed. In other words, Samson relies upon low pressure perfusion that "does not challenge the competence of the aortic valve" instead of blocking the aortic valve with a membrane as claimed.

Accordingly, even if one skilled in the art would have known to combine the teachings of Buckberg and Samson as the examiner alleges, the claimed method and cardioplegia cannula would not have resulted. Withdrawal of the rejection of claims 1 and 3 is solicited. Moreover, as claims 2 and 7 depend from claims 1 and 3, respectively, claims 2 and 7 are allowable for the same reasons as expressed above with respect to claims 1 and 3. Withdrawal of the rejection of claims 1-3 and 7 as being unpatentable as obvious over Buckberg and Samson is thus appropriate and is solicited.

Claims 4-6 stand rejected under 35 USC § 103(a) as allegedly being unpatentable as obvious over Buckberg and Samson further in view of US 6,638,293 ("Makower"). These rejections are also traversed.

As claims 4-6 depend from claim 3, these claims are patentable over Buckberg and Samson for at least the reasons set forth above with respect to claim 3. Moreover, Applicant submits that Makower does not provide any teachings that address the aforementioned deficiencies in the teachings of Buckberg and Samson. The examiner alleges that Makower teaches an umbrella membrane that is opened either using a wire or that springs open where both the wire and umbrella are made of nitinol and that such teachings would have been combined with the teachings of Buckberg and Samson by one skilled in the art to arrive at the claimed methods and cardioplegia cannula. Applicant respectfully disagrees.

Makower discloses a variety of lumen blocking apparatuses that may be delivered transluminally through the patient's vaculature. However, like Buckberg and Samson, Makower does not recognize the problem of aortic valve leakage or provide any solution to such leakage during administration of cardioplegia solution. Also, Makower does not teach a method or cardioplegia cannula configuration whereby the cardioplegia solution is trapped above the deployed membrane and below the cross-clamp so as to force the cardioplegia solution down the coronary arteries as claimed. Accordingly, Makower does not overcome the deficiencies in the teachings of Buckberg and Samson and withdrawal of the rejection of claims 4-6 is thus appropriate.

For at least the reasons set forth herein, claims 1-7 are believed to be allowable over Buckberg, Samson, and Makower. None of the cited art suggests occluding the aortic valve to prevent the leakage of cardioplegia solution into the left ventricle via the aortic valve as claimed. Withdrawal of all rejections is solicited.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims, as amended, are in a condition for allowance. Applicants respectfully request the issuance of a Notice of Allowability.

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